U.S. Food and Drug Administration
Guidance on Labeling for Natural Rubber Latex Condoms
OMB Control No. 0910-0633

SUPPORTING STATEMENT **Part A: Justification**

Terms of Clearance: None.

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations and accompanying guidance. The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, defined by the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Class II devices are defined as devices for which there was insufficient information to show that general controls themselves would provide reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance. The natural rubber latex condoms without spermicidal lubricant are class II devices. Section 513(a)(1)(B) of the FD&C Act defines those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, dissemination and development of guidelines, recommendations, and any other appropriate actions the Agency deems necessary. FDA selected a special controls guidance document as the most effective method for disseminating its labeling recommendations for condoms without spermicidal lubricant.

On December 21, 2000, Congress enacted Public Law 106-554, https://www.congress.gov/106/plaws/publ554/PLAW-106publ554.pdf, which required that FDA "* * * reexamine existing condom labels" and "* * * determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including [human papillomavirus]." Under this mandate, FDA undertook a review of the medical accuracy of condom labeling, which included an extensive review of the scientific information related to condoms. The special controls guidance document includes labeling recommendations based on this FDA review.

We therefore request OMB approval of the information collection provisions discussed in the guidance document and this supporting statement.

2. Purpose and Use of the Information Collection

The primary users of the information disclosed on the label or in the labeling for devices are the health professionals who use or prescribe the device or the lay consumers who use the device. The intent of these rules is that the labeling should contain sufficient information for these persons to use the device safely and effectively. FDA may use the information to determine whether there is reasonable assurance of the safety and effectiveness of the device for its intended use. Failure of the manufacturer, packer, or distributor to label its products in accordance with section 502 of the FD&C Act may result in the product being misbranded under the FD&C Act and the firm and the product subject to regulatory action.

3. Use of Improved Information Technology and Burden Reduction

Manufacturers and repackagers may use any appropriate forms of information technology to develop and distribute the recommended labeling.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency with jurisdiction that can recommend labeling changes to medical devices, which includes male condoms made of natural rubber latex. We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Using the guidelines set by the Small Business Administration on what constitutes a small business (for manufacturing, a small business cannot exceed 500 employees), we estimate that approximately 95% of U.S. medical device manufacturing establishments are considered small businesses.

FDA aids small business and manufacturers by providing guidance and information through the Center for Devices and Radiological Health's Division of Industry and Consumer Education (DICE). DICE provides workshops, onsite evaluations and other technical and nonfinancial assistance to small manufacturers. DICE also maintains a toll-free 800 telephone number and a website that firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

This is a one-time burden for respondents, because once a label is redesigned, it can be used indefinitely.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the *Federal Register* of January 4, 2021 (86 FR 109). No comments were received in response to the notice.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR does not collect personally identifiable information (PII). This ICR is a labeling requirement with no submissions or PII collected.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
"Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300"	5	1	5	12	60

FDA expects approximately five new manufacturers or repackagers to enter the market yearly, and collectively have a third-party disclosure burden of 60 hours. The average burden per disclosure was derived from a study performed for FDA by Eastern Research

Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to design the labeling for OTC drugs is an appropriate proxy for the estimated burden to design condom labeling.

The special controls guidance document also refers to currently approved collections of information found in FDA regulations. The collections of information under 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information under 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

The collection of information in 21 CFR part 801.437 does not constitute a "collection of information" under the PRA. Rather it is a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

12b. Annualized Cost Burden Estimate

	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Label designers	60	$60	$3,600

We estimate the annual cost burden to be approximately $3,600. This is based on the estimated total annual burden hours and the May 2019 Bureau of Labor Statistics (https://www.bls.gov/oes/current/naics4_339100.htm#27-0000) median hourly wage of $29.89 for the profession of 'Designer' (occupation code 27-1020,), in the 'Medical Equipment and Supplies Manufacturing' industry (NAICS code 339100). The wage rate was then doubled to account for benefits and overhead, and rounded to the nearest dollar.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Because FDA's review of this information is conducted as part of the Premarket Notification (510(k)) process, the annualized cost for FDA to review the labels or any other action on the labels is included in, and approved under, OMB control number 0910-0120.

15. Explanation for Program Changes or Adjustments

This is a request for extension without change to the burden hour estimate. There are no adjustments or program changes.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collection will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.